NATIONAL BEER WHOLESALERS ASSOCIATION

David K. Rehr

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April 4, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 02N-0276: FDA/Bioterrorism Preparedness and Response Act of 2002/Registration Proposal

Dear Sir or Madam:

In response to the above-referenced notice of proposed rulemaking by the Food and Drug Administration (FDA), please find enclosed comments made on behalf of the National Beer Wholesalers Association (NBWA).

Should you wish to discuss this matter with me, please feel free to contact me at 703-683-4300. Thank you.

Sincerely,

David K. Rehr

02N-0276

C122

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National Beer Wholesalers Association

David K. Rehr
President

April 4, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 02N-0276: Food and Drug Administration/Bioterrorism Preparedness and Response Act of 2002/Registration Proposal

Dear Sir or Madam:

Re: Comments of Draft Guidelines

In response to the above-reference notice of proposed rulemaking by the Food and Drug Administration (FDA), the National Beer Wholesalers Association (NBWA) welcomes the opportunity to provide comments on the implementation of the registration provision of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act). Representing more than 1,850 beer wholesalers, NBWA is part of the brewing industry that directly or indirectly employs 2.5 million Americans and provides wages and benefits of $60 billion. The brewing industry also pays $14 billion in direct federal, state and local taxes.

NBWA supports a coordinated effort by the FDA and other federal agencies to guard against potential terrorist attacks on or other contamination of the U.S. food supply. To achieve this important goal, a successful FDA strategy will take into account the preexisting and proven regulatory requirements of other agencies that accomplish an identical goal.

A. The registration proposal provision of the FDA notice of proposed rulemaking is duplicative.

A thorough review of the FDA's registration proposal reveals, that with respect to the licensed beverage industry, the intended goal of the Bioterrorism Act has already been met by the Department of Treasury's Tax and Trade Bureau's (TTB) existing obligations. Given that the FDA proposal duplicates the collection of information already required by the TTB, the new FDA proposal would amount to an unnecessary burden not only on the licensed beverage industry but also on the federal government. To finalize redundant and preexisting regulations unduly burdens business while doing nothing to protect and ensure a more secure food supply.

While a safe food supply is the primary goal, it is also important to mention that, as a result of this duplication, FDA's estimate for information collection regarding cost is flawed, due to the fact that it does not take into account that licensed beverage industry members would be required to satisfy two redundant regulatory schemes.

Therefore, when finalizing the implementation of the Bioterrorism Act, NBWA respectfully requests the FDA to further analyze its proposal to determine whether the burden of a duplicative regulation outweighs its benefit. As a remedy for avoiding duplication, the FDA could include express language in the Bioterrorism Act's final registration rule recognizing that the TTB's requirements satisfy the Act's registration requirement.

In an effort to provide the FDA with further details with regard to the licensed beverage industry, it bears mentioning that all persons engaged in the business of producing, importing and distributing licensed beverage products in the United States must obtain a permit from or be registered with the TTB. The TTB and its predecessors have regulated the licensed beverage industry since the 1930s in terms of both import and domestic trade and have maintained a comprehensive set of regulations governing the production, manufacturing, importation and distribution of licensed beverage products. Any applicant for a permit or registration with the TTB is subject to an extensive background and financial investigations review.

Due to this ongoing and well-established practice, producers and wholesalers in the licensed beverage industry already have established relationships with the TTB as well as state and local law enforcement agencies. Additionally, Congress has recognized that the Act called upon functions of other federal agency activities and intended to coordinate all agency functions in implementing the Act. Specifically, Sections 302(c) and 314 of the Act clearly contemplate and direct the efficient use of government resources to effectuate the goals of this Act and to facilitate its implementation by a clear allocation of federal agency activities.

Since the TTB already achieves the desired objectives of the Act's registration requirement, the FDA should coordinate its actions with the TTB to avoid unduly burdening an industry. To do otherwise would result in unnecessary burdens on regulators and businesses and a diversion of valuable government and industry time and resources that could be better used to protect the food supply.

B. Background of additional existing regulations.

Pursuant to section 103 of the Federal Alcohol Administration Act (FAA Act) (27 U.S.C. § 203) and its implementing regulations in 27 C.F.R., the law establishes that it shall be unlawful, except pursuant to a basic permit issued by the Secretary of the Treasury, to engage in the business of producing, importing or wholesaling licensed beverage products. For several reasons, among them the need to ensure that only law abiding persons or those likely to obey the law are issued permits, Section 104 of the FAA Act (27 U.S.C. § 204) prohibits the issuance of a permit to:

- any person who has been convicted of a felony under Federal or State law within the prior five years;

- any person who has been convicted of a misdemeanor under Federal law relating to taxation within the prior three years;

- any person who, by reason of business experience, financial standing or trade connections, is not likely to commence operations within a reasonable period or to maintain such operations in conformity with Federal law; or

- any person whose proposed operations are in violation of the law of the State in which they are to be conducted.

To lend further support to the position that regulations are already in place to help protect against the issuance of licensed beverage permits to persons not suitable, an attached August 30, 2002 FDA comment filed by the former Bureau of Alcohol, Tobacco and Firearms (BATF), states that the licensed beverage permit application process for producer, importer and wholesaler applicants encompasses an extensive investigation of the applicant, including the following:

- verification of citizenship or business visas issued by the Immigration and Naturalization Service (which recently was succeeded by the Department of Homeland Security's Bureau of Immigration and Citizenship Services);

- review of the applicant's business structure to discover any hidden ownership; and

- investigation of investors and owners through multiple criminal databases to discover criminal histories and/or affiliations.

The BATF's August 2002 FDA comment also identified the Bioterrorism Act provisions as redundant with the Bureau's requirements and "encourage[d] collaboration between our respective agencies to avoid duplication of efforts and undue burden upon the alcohol industry."

While brewers and wholesalers are not required to obtain a permit from the TTB, they are required to register with TTB. And while foreign producers are not required to obtain permits or register with the TTB, they can only import licensed beverage through an entity that holds a Federal Basic Importer's Permit. Further, the importer is routinely required to produce letters from the foreign supplier about the product as part of the application process.

Turning to state authority and regulation, an applicant for registration with the TTB must also obtain a license or permit from each state in which it does business. State regulators also subject licensed beverage permit applicants to a thorough application and review process, and many state regulators have police powers and regular contact with federal law enforcement officials.

Additionally, the Internal Revenue Code and its implementing regulations that are also administered by the TTB require that persons wishing to establish operations as a distilled spirits plant (DSP), bonded winery (BW) or brewer also must qualify to engage in such operations. See, e.g., Subpart G of 27 C.F.R. Part 19 (DSP); Subpart D of 27 C.F.R. Part 24 (BW); and Subpart G of 27 C.F.R. Part 25 (Brewery).

Multiple taxes, including federal, state, and local excise taxes, sales taxes, and other special taxes apply to license beverage products. Conversely, many of these same taxes do not apply to other foods and beverages categories. Because of these additional and different taxes, licensed beverage products and the registration of these products is tracked more carefully by all levels of government as well as those in the licensed beverage industry. Federal tracking requirements are codified in regulations promulgated under the Federal Alcohol Administration Act.

Undocumented transfers among wholesalers or retailers and shipments of damaged goods in secondary markets are also considered to be areas ripe for potential problems. These identified transactions are generally illegal among suppliers, wholesalers and retailers of licensed beverages, and industry participants, in particular beer wholesalers, are not likely to endanger their licenses or their businesses by participating in the concerned activity. Additionally, federal and state tax refund systems are available for products removed from commerce due to age, damage, destruction or natural disasters, offering a financial and business incentive to comply with the law.

Finally, the TTB and the FDA jointly have established guidelines in the form of a Memorandum of Understanding dealing with a variety of matters where the statutory responsibilities of the two agencies overlap. By simply updating that Memorandum, the FDA can focus on other food and beverage categories where no existing regulatory or registration system is in place.

Conclusion

When other federal agency regulations allow for a more effective and reliable means of addressing the FDA registration proposal, the FDA has the authority to coordinate its regulations with other federal agencies. There is no evidence to contradict the position that the TTB would cooperate and coordinate registration information with the FDA and that it would address the need to ensure communications with the licensed beverage industry in the event of a potential threat.

Therefore, the FDA should reconsider is proposed rulemaking on registration and determine a plan for proper coordination with the TTB to ensure that there is no duplication of government resources or efforts. The FDA should further include express language in the Bioterrorism Act's final registration rule that addresses this matter and recognizes that preexisting TTB licensed beverage registration requirements adequately address registration requirement under the Bioterrorism Act. Doing so will allow the FDA, the federal government and those in the licensed beverage industry to channel important time, effort and resources toward addressing the security concerns related to other areas and categories of the U.S. food supply.

In closing, I would like to thank you for the opportunity to provide comments on the FDA effort to implement the registration provision of the Bioterrorism Act. NBWA appreciates the efforts being made by those at FDA to effectively and efficiently resolve this area of regulatory duplication and offers any additional assistance FDA may deem necessary to finalize regulations directed by the Bioterrorism Act. If I can be of any further assistance, please do not hesitate to contact me at 703-683-4300.

Sincerely,

David K. Rehr

David K. Rehr
President

Enclosures

(ATTACHMENT)

August 30, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: (1) Section 303 – Docket No. 02N-0275 (Detention)
(2) Section 305 – Docket No. 02N-0276 (Registration)
(3) Section 306 – Docket No. 02N-0277 (Recordkeeping)
(4) Section 307 – Docket No. 02N-0278 (Prior Notice)

Dear Sir/Madam:

The undersigned are a coalition of trade associations (see Attachment A) representing all tiers of the beverage alcohol industry. Members of our associations are involved in the production, importation, distribution/wholesaling, and retailing of beverage alcohol products that are sold throughout the United States.

On behalf of our respective members, we welcome the opportunity to provide initial comments concerning the Food and Drug Administration's (FDA) proactive efforts to liaise with the foods community in implementing the provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Act). We fully support this FDA initiative, which is designed to create a focused regulatory scheme that does not unnecessarily duplicate existing statutory and/or regulatory requirements currently in place. To that end, our comments focus upon how the directives of the above-referenced Sections of the Act already are met and satisfied by the existing extensive regulatory scheme governing beverage alcohol.

Since the 1930s, the Bureau of Alcohol, Tobacco and Firearms (BATF) and its predecessor agencies have regulated the beverage alcohol industry in terms of both import and domestic trade.[1] BATF has a comprehensive set of regulations that governs the production, manufacture, importation, and distribution of beverage alcohol products. All persons engaged in the business of producing, importing and distributing beverage alcohol products in the United States must obtain a permit from BATF or be registered with BATF. The beverage alcohol industry also is governed by an extensive regulatory scheme administered by BATF, which, among other things, requires industry members to strictly account for all products. Simply put, the existing regulations enforced by BATF more than satisfy the provisions of this Act.

[1] See generally, Federal Alcohol Administration Act, 27 U.S.C. §§ 121-211, Internal Revenue Code 26 U.S.C. §§ 5001-5691, and Title 27, Code of Federal Regulations.

In addition, industry members involved in the production, importation and distribution of beverage alcohol products are licensed by each State in which they do business. Each State also has regulations that require recordkeeping and mandate the filing of periodic reports of beverage alcohol products shipped into and/or sold in that State. Although excluded from the scope of the Act, beverage alcohol retailers also are licensed by the States in which they do business.

The U.S. Customs Service further regulates importers of beverage alcohol products. Importers must maintain records to establish upon request that goods imported have been classified correctly, taxes have been paid, and the importer of record has complied with all regulations specifically dealing with beverage alcohol. Further, as discussed more fully below, Customs has several initiatives in place, such as the Container Security Initiative, that requires extensive information about U.S. bound shipments at least 24 hours before the vessel sails to the United States.

We urge FDA to avoid proposing or adopting regulations that would be duplicative of regulations already in place and administered by other federal agencies. In that regard, Sections 302(c) and 314 clearly contemplate and direct the efficient use of government resources to effectuate the goals of this Act and to facilitate its implementation by a clear allocation of federal agency activities. This clear allocation of responsible action among federal agencies, such as BATF and the Customs Service vis-à-vis their respective regulatory schemes governing beverage alcohol, will best utilize the procedures and processes already in place to most efficiently "develop a crisis communications and education strategy with respect to bioterrorist threats to the food supply," the stated purpose of Title III of the Act.

Duplicative regulations and unnecessary regulations are costly and create inefficiencies, as well as spawn potential confusion within the regulated community. Further, such measures impose unnecessary burdens upon regulators and the regulated community and thereby divert valuable time and resources away from government and industry efforts to protect the food supply from bioterrorist threats -- an objective that all of us fully support.

Finally, we urge that the resources and appropriations allocated to implement the Act be available to the federal agencies, such as BATF, that are a critical component in effectuating its provisions. In addition, such agencies also should have available the necessary resources and funds to meet various procedural elements of the Act, such as the electronic filing directive set forth in Section 305(d).

The following are our comments regarding specific Sections of the Act.

Section 303 – Administrative Detention

No person can hold a federal permit to produce, import or distribute beverage alcohol if that person has been convicted of a felony within five years prior to the date of application or within three years of the date of application to have been convicted of a misdemeanor relating to beverage alcohol. Without a permit, importers, distillers, vintners, and distributors cannot

engage in the beverage alcohol business. Permits can be revoked or suspended for reasons specified in federal law. The current permit system for beverage alcohol producers, importers and wholesalers/distributors is far more restrictive and gives the government greater control than anything contemplated in instant Act.

Section 305 – Registration of Food Facilities

Requiring a producer, importer, or distributor of beverage alcohol to register with FDA would be a duplication of existing licensing and/or permit requirements. All importers, domestic producers and wholesalers/distributors of beverage alcohol must obtain a permit from the federal government. While brewers are not required to obtain a permit, they must register with BATF. Any applicant for a permit or registration with BATF must go through extensive background and financial investigations. Foreign producers can only import beverage alcohol through an entity that holds a Federal Basic Importer's Permit.

Section 306 – Maintenance and Inspection of Records for Foods

Under current federal laws and regulations, importers, producers and distributors/ wholesalers of beverage alcohol must maintain "one up and one down" records. During normal business hours, these records must be kept and made available for review by a federal officer. The objectives of Section 306 are met or exceeded by current BATF recordkeeping requirements/regulations. Any additional recordkeeping requirement by FDA would be duplicative and unnecessary.

Section 307 – Prior Notice of Imported Food Shipment

The U.S. Customs Service already receives advance notice of the arrival of a ship and of the ship's manifest well in advance of the ship's arrival. Given the Customs Service's various security initiatives, there is no need for FDA to issue more regulations that would require something already required by the U.S. Customs Service. For example, Customs is in the process of finalizing its new requirements that would require ocean carriers and non-vessel-operating common carriers to present detailed cargo manifests 24 hours before a container is loaded onto a ship. Shippers – food importers – play a crucial role in satisfying these requirements.

The Customs' checklist requires fifteen (15) information elements that are far more detailed than the directives of the Act. These information elements are: (1) foreign port of departure; (2) carrier SCAC code; (3) voyage number; (4) date of scheduled arrival in first U.S. port; (5) numbers and quantities from carrier's master or house bill of lading; (6) first port of loading, or first port of receipt, of the cargo by the inbound carrier; (7) a precise description (or the Harmonized Tariff Schedule numbers if the HTS classification is provided by the shipper) and weight of the cargo, or, if the container is sealed, the shipper's declared description and weight of the cargo (generic descriptions, specifically freight-all-kinds, general cargo, and STC (said to contain) are not acceptable); (8) shipper's name and address, or an identification number, from all bills of lading; (9) consignee's name and address, or the owner's or owners' representative's name and address, or an identification number, from all bills of lading; (10) advise Customs when actual boarded quantities do not equal quantities indicated on the relevant bills of lading (carriers

are not required to verify quantities in sealed containers); (11) vessel name, national flag and vessel number; (12) foreign country of origin where cargo is loaded onto vessel; (13) hazardous-material indicator; (14) container number (for containerized shipments); and (15) seal number affixed to container.

Customs' efforts to improve security impose requirements beyond the dictates set forth in the Act. U.S. companies must educate their suppliers not only about the new manifest rules referenced above, but also about the Customs-Trade Partnership Against Terrorism (C-TPAT) and other security measures. Although technically a voluntary program, C-TPAT is becoming an industry standard.

Conclusion

In summary, we recommend that FDA meet with other agencies that have regulations and jurisdictions to govern the importation, production and distribution of beverage alcohol in order to coordinate responsibilities. Such a liaison will avoid duplication of government resources, government manpower and government regulation. We submit that this suggested course of action will enable the federal government and the food industry to focus their resources more efficiently and effectively upon efforts that will enhance security and will avoid unnecessary and redundant burdens that otherwise could be imposed upon both enforcement and compliance efforts.

Thank you for the opportunity to present our views concerning FDA's actions to implement the Bioterrorism Act. We stand ready to work with you at any time to assist FDA in the development of implementing regulations that will result in the efficient and effective implementation of this Act. If we can be of any further assistance, please do not hesitate to call on us.

Sincerely,

Arthur DeCelle, Executive Vice President & General Counsel
Beer Institute

C. M. Wendell Lee, General Counsel
Wine Institute

Donald MacVean, Executive Director
The Presidents' Forum

Robert J. Maxwell, President
National Association of Beverage Importers, Inc.

Bill Nelson, Vice President - Government Relations
American Vintners Association

Lynne J. Omlie, Senior Vice President & General Counsel
Distilled Spirits Council of the United States, Inc.

David K. Rehr, President
National Beer Wholesalers Association

Harry Wiles, Executive Director
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Craig Wolf, General Counsel
Wine and Spirits Wholesalers of America, Inc.